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10/809,767	03/24/2004	Sean S. Suh	001227/0125	7927

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STROOCK & STROOCK & LAVAN, LLP
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NEW YORK, NY 10038

EXAMINER

HARVEY, JULIANNA NANCY

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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07/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,767	Applicant(s) SUH ET AL.	
	Examiner Julianna N. Harvey	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 20-31, 34-38 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 10, 20-24 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 11-17, 25-31 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

The objection to claims 29 and 30 has been withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 8, 9, 12, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Russo et al. (US 4,140,161 A).

Regarding **claim 1**, Russo et al. disclose a bone fastener implantation and removal system comprising: a bone plate (35; col. 6, lines 14-17) including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners (17) receivable within the fastener holes formed in the bone plate; and a tool (10) including: a drive shaft (11, 16) having proximal and distal ends, an intermediate portion, an outer sleeve engaging portion and a length; a handle portion associated with the drive shaft proximal end; a fastener engaging portion associated with the drive shaft distal end, the fastener engaging portion comprising a first surface configured to axially engage one of the plurality of

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fasteners and a second surface configured to rotationally engage the fastener; and an outer sleeve (19, 22) associated with the drive shaft intermediate portion, the sleeve comprising a proximal end, a distal end and a drive shaft engaging portion, the distal end contacting the top surface of the bone plate to apply a force to the top surface of the bone plate to facilitate removal of the fastener from the fastener holes; wherein the outer sleeve engaging portion and the drive shaft engaging portion are configured to coact to allow at least a portion of the drive shaft to translate linearly within the sleeve (Fig. 1 inset; Fig. 7 inset; Fig. 4). Regarding **claim 2**, Russo et al. disclose that the drive shaft (11, 16) comprises a cannulated fastener driving portion (16) and an inner shaft portion (11), at least a portion of the inner shaft portion being slidably disposed within the fastener engaging portion, the inner shaft portion being configured to axially engage the fastener while the fastener driving portion is configured to rotationally engage the fastener (Fig. 1). Regarding **claim 6**, Russo et al. disclose that the inner shaft portion (11) is tapered and the cannulated fastener driving portion (16) is configured to slidably receive the tapered inner shaft (Fig. 7 inset). Regarding **claim 8**, Russo et al. disclose that the first surface comprises at least one radial member configured to axially engage a recess in a head of the fastener (17) (Fig. 7 inset). Regarding **claim 9**, Russo et al. disclose that the first surface comprises a plurality of radial members, each of which is configured to axially engage corresponding recesses in the fastener head (Fig. 7 inset). Regarding **claim 12**, Russo et al. disclose an inner shaft (11) having a fastener engaging surface ("First Surface") at one end, the drive shaft further comprising a cannulation (16 is cannulated) configured and sized to accept at least a portion of the

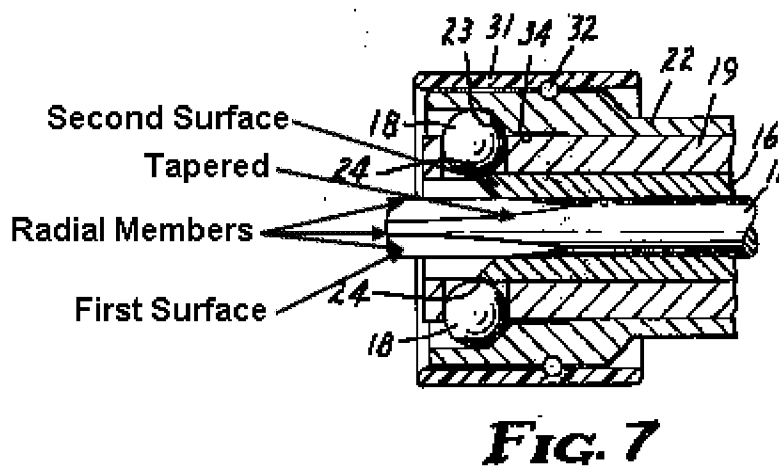
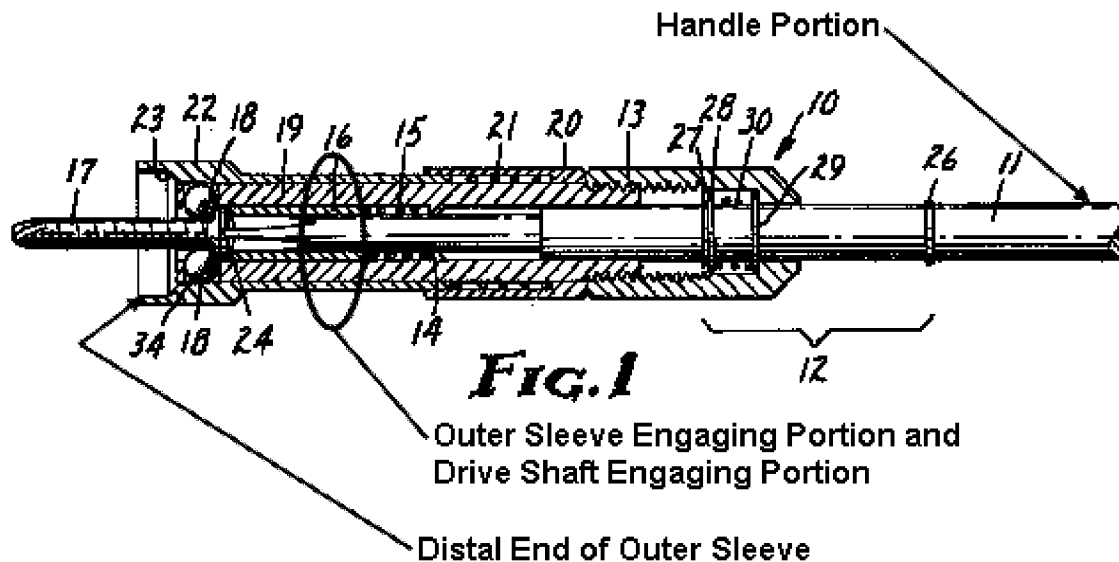
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inner shaft, wherein when the inner shaft is disposed within the cannulation the fastener engaging surface extends distally beyond the distal end of the drive shaft (Fig. 7 inset).

Regarding **claim 43**, Russo et al. disclose a bone fastener implantation and removal system comprising: a bone plate (35; col. 6, lines 14-17) including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of bone fasteners (17) receivable within the fastener holes formed in the bone plate; and a tool (10) including: an inner shaft (11) for engaging one of the bone fasteners, an outer shaft (16) for engaging the bone fastener, and an outer sleeve (19, 22) for contacting the top surface of the bone plate and applying a force to the top surface of the bone plate to facilitate removal of one of the plurality of fasteners from the fastener holes; wherein the inner shaft is configured to axially engage the bone fastener and is slidably disposed within the outer shaft; wherein the outer shaft is configured to rotationally engage the bone fastener and further comprises an outer sleeve engaging portion; and wherein the outer sleeve further comprises an outer shaft engaging portion ("Drive Shaft Engaging Portion") such that the shaft may translate linearly within the outer sleeve when the outer sleeve engaging portion rotationally engages the outer shaft engaging portion (Fig. 1 inset).

See following page for Figs. 1 and 7 of Russo et al.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Frigg et al. (US 2003/0036758 A1). Russo et al. disclose the claimed invention except that the axial fastener-engagement portion comprises a thread. However, Russo et al. show that the recess in the head of the fastener (17) complements the axial fastener-engagement portion ("First Surface") (Fig. 7 inset above; Fig. 4). Frigg et al. teach that the recess in the head of a fastener can be an internally threaded recess to receive a complementary driving tool (para. 0033). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Russo et al. such that the recess in the head of the fastener and the axial fastener-engagement portion are threaded, as suggested by Frigg et al., as doing so is merely a simple substitution of one known element for another to obtain predictable results.

Claims 11 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Bryant et al. (US 5,649,931 A). Russo et al. disclose the claimed invention except that the sleeve engaging portion and shaft engaging portions comprise complementary threads (**claims 11 and 45**). Bryant et al. teach a bone fastener implantation and removal tool comprising: a drive shaft (14, 16) having a sleeve engaging portion (38) and an outer sleeve (18) having a shaft engaging portion (36) wherein the sleeve engaging portion and shaft engaging portions comprise complementary threads (Figs. 4-5; col. 3, lines 17-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Russo et al. such that the sleeve engaging portion and shaft engaging portions comprise

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complementary threads (**claims 11 and 45**), as suggested by Bryant et al., as doing so is merely a combination of prior art elements according to known methods to yield predictable results.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Burke (US 5,431,660 A). Russo et al. disclose the claimed invention except that at least a portion of the sleeve has a roughened outer surface. Burke teaches a bone fastener implantation and removal tool comprising an outer sleeve (84, 86) that can linearly translate with respect to a drive shaft (70) wherein the outer sleeve is provided with a roughened outer surface to allow the user to better grasp the outer sleeve (col. 7, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the outer sleeve of Russo et al. with a roughened outer surface, as suggested by Burke, as doing so allows the user to better grasp the outer sleeve.

Claims 14-17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Bailey et al. (US 2002/0151899 A1).

Regarding **claim 14**, Russo et al. disclose that the fastener engaging portion further comprises a locking clip expanding portion ("Second Surface"), that the fastener (17) is disposed within the fastener holes formed in the plate (35), and that the locking clip expanding portion is configured to expand the locking clip (Fig. 7 inset; Fig. 4).

Regarding **claim 15**, Russo et al. disclose that the locking clip expanding portion is configured to expand the locking clip to a dimension greater than an outer dimension of the fastener head. Regarding **claim 16**, Russo et al. disclose that the locking clip

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expanding portion is configured to expand the locking clip to a dimension smaller than an outer diameter of the fastener head. Regarding **claim 44**, Russo et al. disclose that the outer shaft (16) includes a fastener engaging end ("Second Surface") for rotationally engaging the bone fastener (17), that the bone fastener is disposed within one of the plurality of fastener holes formed in the plate (35), and that the fastener engaging end is configured to expand the fastener locking clip when the outer shaft engages one of the plurality of fasteners (Figs. 4-5). Russo et al. fail to disclose that the fastener hole is provided with an expandable locking clip configured to engage a portion of the fastener to prevent the fastener from being backed out of the fastener hole (**claim 14**), that at least a portion of the fastener is configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate (**claim 17**), and that the plate has an expandable locking clip disposed within the fastener hole, the clip configured to engage a portion of one of the plurality of fasteners to prevent one of the plurality of fasteners from backing out of the one of the plurality of fastener holes (**claim 44**). Bailey et al. teach a bone plate (12) and a plurality of fasteners (14) disposed within fastener holes in the plate (Fig. 4). Bailey et al. also teach a locking clip (16) disposed within each of the fastener holes to prevent the fasteners from backing out of the plate (Fig. 4; para. 0032). Bailey et al. also teach a tool (90) configured to remove the fastener from the plate (Fig. 10). Furthermore, at least a portion of the fastener is configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the removal tool is

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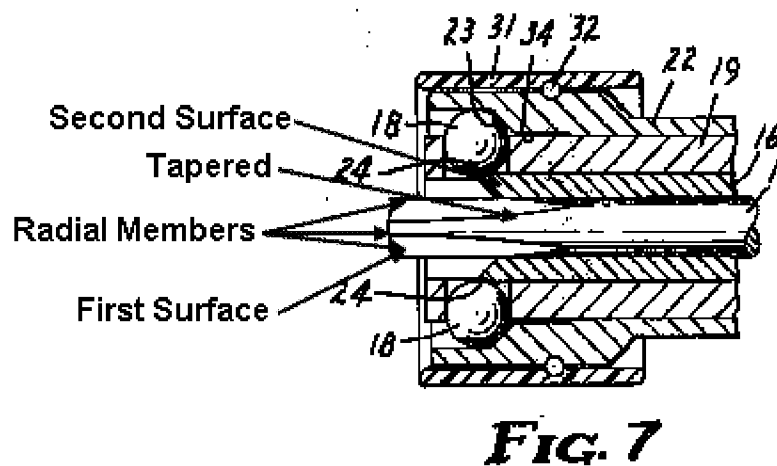
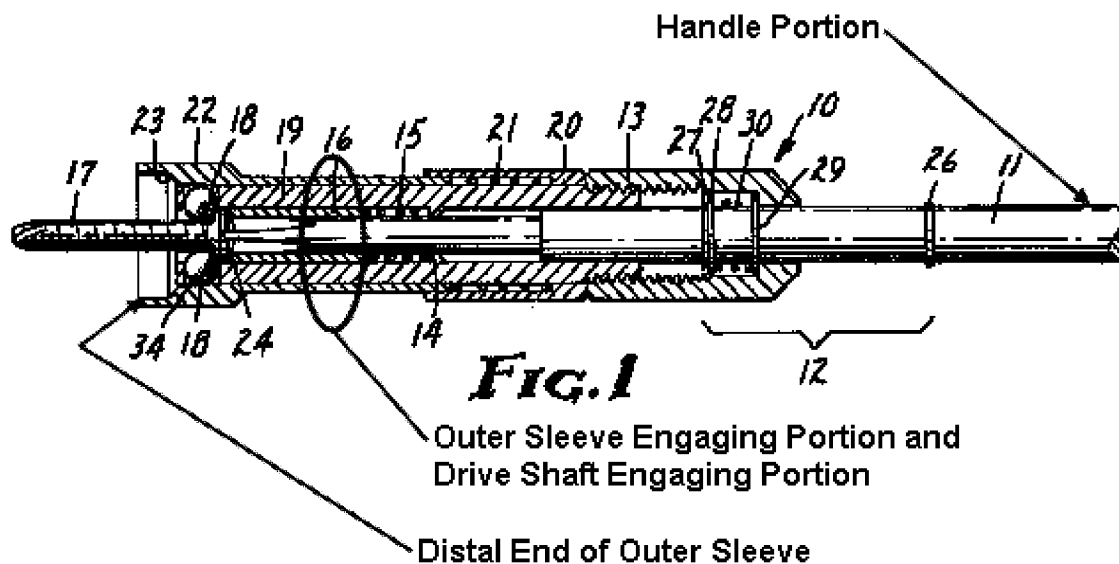
operated to remove the fastener (Fig. 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Russo et al. plate with locking clips that engage the fasteners when they are disposed within the fastener holes (**claims 14 and 44**), as suggested by Bailey et al., as doing so prevents backout of the fastener. It would have been further obvious that a portion of the fastener must be configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate (**claim 17**), as shown by Fig. 10 of Bailey et al., as the locking clip must stay expanded to a diameter substantially equal to that of the fastener to allow complete removal of the fastener.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Bryant et al. (US 5,649,931 A). Regarding **claim 25**, Russo et al. disclose a bone fastener implantation and removal system comprising: a bone plate (35; col. 6, lines 14-17) including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners (17) receivable within the fastener holes formed in the bone plate; and a tool (10) including: a drive shaft (11, 16) having a fastener engaging end and a sleeve engaging portion ("Outer Sleeve Engaging Portion"), the fastener engaging end comprising a rotational engagement portion ("Second Surface") and an axial engagement portion ("First Surface"); a sleeve (19, 22) disposed about at least a portion of the drive shaft, the sleeve comprising a proximal end, a distal end and a drive

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shaft engaging portion, the distal end contacting the top surface of the bone plate to apply a force to the top surface of the bone plate to facilitate removal of one of the plurality of fasteners from the fastener holes; wherein the drive shaft can translate linearly within the sleeve when the drive shaft is rotated relative to the sleeve (Fig. 1 inset; Fig. 7 inset; Fig. 4). Regarding **claim 26**, Russo et al. disclose that the drive shaft (11, 16) comprises a cannulated fastener driving portion (16) and an inner shaft portion (11), at least a portion of the inner shaft being slidably disposed within the driving portion, the inner shaft portion being configured to axially engage one of the fasteners while the driving portion is configured to rotationally engage the fastener (Fig. 1; Fig. 7 inset). Regarding **claim 27**, Russo et al. disclose that the inner shaft portion (11) is tapered and the cannulated fastener driving portion (16) is configured to slidably receive the tapered inner shaft (Fig. 7 inset). Russo et al. fail to disclose that the sleeve engaging portion and the drive shaft engaging portion comprise complementary threads (**claim 25**). Bryant et al. teach a bone fastener implantation and removal tool comprising: a drive shaft (14, 16) having a sleeve engaging portion (38) and a sleeve (18) having a shaft engaging portion (36) wherein the sleeve engaging portion and shaft engaging portions comprise complementary threads (Figs. 4-5; col. 3, lines 17-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Russo et al. such that the sleeve engaging portion and shaft engaging portions comprise complementary thread (**claims 25**), as suggested by Bryant et al., as doing so is merely a combination of prior art elements according to known methods to yield predictable results.

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Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo et al. (US 4,140,161 A) in view of Bryant et al. (US 5,649,931 A) as applied to claim 25 above, and further in view of Bailey et al. (US 2002/0151899 A1). Regarding **claim 28**, Russo et al. disclose that the fastener engaging end further comprises a locking clip expanding portion ("Second Surface"), that the fastener engaging end of the

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drive shaft (11, 16) is configured to engage one of the plurality of fasteners (17) disposed within one of the plurality of fastener holes formed in the plate (35), and that the fastener engaging end is configured to expand the fastener locking clip when the drive shaft engages the fastener (Fig. 7 inset above; Fig. 4). Regarding **claim 29**, Russo et al. disclose that the locking clip expanding portion is configured to expand the locking clip to a dimension greater than an outer dimension of the fastener head. Regarding **claim 30**, Russo et al. disclose that the locking clip expanding portion is configured to expand the locking clip to a dimension smaller than an outer diameter of the fastener head. Russo et al. and Bryant et al. fail to teach that the plate has an expandable locking clip disposed within the fastener hole, the clip configured to engage a portion of the fastener to prevent the fastener from backing out of the fastener hole (**claim 28**), and that when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate, an axial removal force applied by the tool is greater than a fastener locking force of the locking clip (**claim 31**). Bailey et al. teach a bone plate (12) and a plurality of fasteners (14) disposed within fastener holes in the plate (Fig. 4). Bailey et al. also teach a locking clip (16) disposed within each of the fastener holes to prevent the fasteners from backing out of the plate (Fig. 4; para. 0032). Bailey et al. also teach a tool (90) configured to remove the fastener from the plate (Fig. 10). As such, the axial removal force applied by the tool must be greater than the fastener locking force of the clip in order to successfully remove the fastener. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Russo et al. plate with locking clips that engage the fasteners when

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they are disposed within the fastener holes (**claim 28**), as suggested by Bailey et al., as doing so prevents backout of the fastener. As stated above, the axial removal force applied by the tool must be greater than the fastener locking force of the clip in order to successfully remove the fastener (**claim 31**).

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6-9, 11-17, 25-31, and 43-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733